



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 21-24]

Lewisville Medical Pharmacy; Decision and Order

I. Introduction

On June 9, 2021, the United States Department of Justice, Drug Enforcement Administration (hereinafter, Agency) issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter collectively, OSC) to Lewisville Medical Pharmacy (hereinafter, Respondent) of Lewisville, Texas. OSC, at 1-2, 11. The OSC immediately suspended, and proposed the revocation of, Respondent's Drug Enforcement Administration (hereinafter, DEA) registration No. FL2190332, pursuant to 21 U.S.C. 824(d) and (a)(4), respectively, "because . . . [Respondent's] continued registration constitutes 'an imminent danger to the public health or safety'" and "because . . . [Respondent's] continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f)." *Id.* at 1. The OSC more specifically alleged that, according to Respondent's "dispensing information" from at least March 2, 2018, through at least March 20, 2021, Respondent "repeatedly filled prescriptions for Schedule III through V controlled substances in the face of obvious and unresolved red flags of drug abuse and diversion [hereinafter, red flags], and therefore, in violation of both federal and Texas law," including 21 CFR 1306.04(a) and Texas Health & Safety Code § 481.074(a).¹ *Id.* at 2. The OSC includes allegations about pattern prescribing (which it defines as prescribing the same controlled substance in identical or substantially similar quantities to multiple individuals indicating a lack of individualized therapy), distance (which it defines as traveling abnormally long distances to fill a controlled substance prescription), cash payment (which it defines as a

¹ The Agency is only adjudicating controlled substance prescriptions in the record that are dated on or after September 16, 2018. See 22 TAC § 291.29 (effective September 16, 2018).

common red flag of abuse and diversion as it permits an individual to avoid scrutiny associated with the use of insurance as part of the payment process), and shared address (which it defines as multiple persons with the same address presenting the same or substantially similar controlled substance prescriptions from the same practitioner) red flags.² *Id.* at 4-10.

Respondent timely requested a hearing. Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, RD), at 1. DEA Administrative Law Judge Paul E. Soeffing (hereinafter, ALJ) conducted a four-day video teleconference hearing from November 15 through 18, 2021. *Id.* On April 1, 2022, the ALJ issued his RD, recommending revocation of Respondent's registration.³ *Id.* at 57.

Having thoroughly analyzed the record and applicable law, the Agency summarizes its findings and conclusions: (1) the Diversion Control Division (hereinafter, Government) presented a *prima facie* case, (2) Respondent attempted, but failed, to rebut the Government's *prima facie* case, and (3) substantial record evidence, including the testimony of the Government's expert witness and large portions of the testimony of Respondent's owner and Pharmacist-in-Charge (hereinafter, PIC), shows Respondent's violations of applicable law, violations against a foundation of the Controlled Substances Act (hereinafter, CSA). Accordingly, the Agency will revoke Respondent's registration. *Infra*, Order.

II. FINDINGS⁴

A. The Government's Case

The Government's principal case presented two witness – a Diversion Investigator and its expert, Diane Ginsburg, Ph.D., whom the ALJ accepted, without objection, as an expert in Texas

² The phrase "red flag" is used in the record before the Agency with varying accuracy. The testimony of the Government's expert accurately defines the phrase and a Texas pharmacist's obligation when presented with a controlled substance prescription, that is, consistent with federal law. *See, e.g.*, Tr. 555-56; *infra*, section II.A. The use of the phrase in Respondent's case, on the other hand, is not always fully accurate. *Infra*, section II.B. When Respondent's case accurately acknowledges circumstances that are red flags, it rarely states a Texas pharmacist's ensuing obligation accurately. *Id.* When Respondent uses the phrase when questioning the Government's expert, the context out of which the expert responds is an accurate understanding of the phrase regardless of what Respondent meant by its question.

³ Neither party filed exceptions to the RD.

⁴ The Agency incorporates the parties' Stipulations and accepts them as fact. RD, at 2-3. The first and second stipulations address Respondent's DEA registration and its status. *Id.* at 2.

retail pharmacy practice and Texas pharmacy practice.⁵ Tr. 21-85 (DI testimony), *id.* at 85-559 (Dr. Ginsburg testimony). Having thoroughly analyzed the record and applicable law, the Agency agrees with the RD and finds that Dr. Ginsburg “presented credible testimony that was internally consistent and logically persuasive, . . . [and] an objective analysis . . . [admitting] times where . . . she may not have identified a red flag.” RD, at 18. The Agency agrees with the RD and affords Dr. Ginsburg’s testimony “significant weight” in this adjudication. *Id.*

The Agency finds that Dr. Ginsburg’s testimony about the red flags alleged in the OSC constitutes a portion of the substantial record evidence that Respondent filled controlled substance prescriptions exhibiting red flags without documenting the resolution of those red flags, thereby violating applicable legal requirements.⁶ *E.g.*, Tr. 108-120, 122-56, 169-90, 219-57, 261-72, 277-86, 506, 518, 553, 556; *accord, e.g.*, RD, at 8-11, 13-18, 34-37, 41-45, 47-48.

B. The Respondent’s Case

Respondent’s owner and PIC, whom Respondent characterized as “an expert on Texas pharmacy law and practice,” was the only witness Respondent presented.⁷ Respondent’s Prehearing Statement, at 4; Tr. 561-849.⁸ Having thoroughly analyzed the record and applicable law, the Agency finds that Respondent’s owner and PIC is the witness with the most at stake in this adjudication. The Agency finds that, while the testimony of Respondent’s owner and PIC does include reliable statements, it also includes statements that lack credibility, are implausible, and/or are not persuasive. The Agency finds that the testimony of Respondent’s owner and PIC must be considered with much caution, and where his testimony conflicts with credible record

⁵ In rebuttal, the Government presented one witness, the undercover Task Force Officer. Tr. 850-95.

⁶ Dr. Ginsburg testified that a “red flag is something that would raise suspicion or cause you concern related to a medication and certainly there are those that have been identified, as well as types of things that are considered red flags, federally, as well as within our State that pharmacists are aware of” and that the “obligation is to verify validity and then to document the resolution of that red flag.” Tr. 555-56; *see also* RD, at 41.

⁷ At the hearing, however, Respondent did not proffer its owner and PIC as an expert. Respondent’s owner and PIC testified that he is “legally responsible” for ensuring that Respondent, its operations, its policies, and “everything” go “according to the rule and the law.” Tr. 564. He also testified that he filled the controlled substance prescriptions at issue in this adjudication. Tr. 848.

⁸ As the parties’ closing briefs do not challenge any of the ALJ’s pre-hearing or hearing rulings, and as neither party filed exceptions, the Agency need not address, and does not address, any of those rulings in this Decision/Order.

evidence or applicable law, the Agency does not credit it. *Supra*, section II; *infra*, sections III, IV.B., and V; *see also* RD, at 27.

The Agency finds substantial record evidence that (1) the testimony of Respondent's owner and PIC includes his unsupported and previously undocumented statements justifying, in retrospect, the legitimacy of controlled substance prescriptions that Respondent filled, (2) the testimony of Respondent's owner and PIC includes his ensuing conclusions that there is no red flag on those controlled substance prescriptions, (3) the testimony of Respondent's owner and PIC includes his admissions that he did not document the existence or resolution of any red flag on those controlled substance prescriptions since, according to him, there were no red flags on the controlled substance prescriptions and, when there is no red flag on a controlled substance prescription, there is "nothing to document," and (4) Respondent filled controlled substance prescriptions without documented resolution of the red flags on them.⁹ *E.g.*, Tr. 654-56, 664-79, 714-32, 738-53, 758-75, 779-85; *see also, e.g.*, Respondent's Closing Brief with Proposed Findings of Fact and Conclusions of Law (hereinafter, Resp Posthearing), at 1-2 ("With a few exceptions, . . . [Respondent] denies such red flags were present for the prescriptions at issue."); RD, at 33 n.33, 40-51, 53-54.

III. Texas Pharmacists' Professional Responsibility¹⁰

According to the CSA, "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute, . . . dispense, or possess with intent to . . . distribute[] or dispense, a controlled substance." 21 U.S.C. 841(a)(1). The CSA's implementing regulations state that a lawful controlled substance order or prescription is one that

⁹ "[A] corresponding responsibility rests with the pharmacist who fills the prescription." 21 CFR 1306.04(a).

The testimony of Respondent's owner and PIC about "red flags" and "potential red flags" is not fully accurate. He testified at length on multiple occasions about why, in his view, there is no red flag on a given controlled substance prescription at issue in this proceeding. *E.g., infra*, sections II.B., III., and IV.B. His testimony lacks legal and factual credibility particularly because Texas law explicitly lists and clearly articulates what red flags are, making the identification of red flags on controlled substance prescriptions a process largely devoid of professional analysis or judgment, and because the applicable standard of practice requires the resolution of those red flags and the documentation of the red flags' resolutions before the controlled substance prescription is filled. *Supra*, section II.A.; *infra*, sections III and IV.B.

¹⁰ *See also* 22 TAC § 291.33 (Texas drug utilization review requirement); RD, at 34-35.

is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice” and that, while the “responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner,” a “corresponding responsibility rests with the pharmacist who fills the prescription.” 21 CFR 1306.04(a); *The Pharmacy Place*, 86 FR 21,008, 21,012-14, 21,034-35 (2021) (requisite scienter under 21 CFR 1306.04(a)).

The OSC is addressed to Respondent at its registered address in Texas. Therefore, the Agency also evaluates Respondent’s actions according to Texas law, including the applicable Texas pharmacists’ professional responsibilities.¹¹

During the period alleged in the OSC, Texas law specifically addressed pharmacists’ professional responsibilities concerning red flags. First, according to Texas law, pharmacists “shall make every reasonable effort to ensure that any prescription drug order . . . has been issued for a legitimate medical purpose by a practitioner in the course of medical practice.” 22 TAC § 291.29(b); *The Pharmacy Place*, 86 FR at 21,012. Further, according to Texas law, a “pharmacist shall make every reasonable effort to prevent inappropriate dispensing due to fraudulent, forged, invalid, or medically inappropriate prescriptions in violation of a pharmacist’s corresponding responsibility” and lists “red flag factors” that are “relevant to preventing the non-therapeutic dispensing of controlled substances” that “shall be considered by evaluating the totality of the circumstances rather than any single factor.” 22 TAC § 291.29(f); *The Pharmacy Place*, 86 FR at 21,012; *see also* Resp Posthearing, at 2-3, 4. A pharmacy’s “dispens[ing]” a “reasonably discernible pattern of substantially identical prescriptions for the same controlled substance . . . for numerous persons, including a lack of individual drug therapy in prescriptions issued by the practitioner” is the first red flag listed. 22 TAC § 291.29(f)(1). Other red flags explicitly identified in Texas law that are relevant to this proceeding are “multiple persons with the same address [who] present substantially similar controlled substance prescriptions from the

¹¹ *See Gonzales v. Oregon*, 546 U.S. 243, 269-71 (2006); *see also* OSC, at 2-3.

same practitioner” and “persons [who] consistently pay for controlled substances with cash or cash equivalents more often than through insurance.” 22 TAC § 291.29(f)(11) and (12).

Dr. Ginsburg’s testimony, including her explanations of the standard of practice of Texas pharmacies and Texas pharmacists’ professional responsibilities, is consistent with this legal analysis and states that the applicable standard of practice is for the resolution of red flags to be documented before the controlled substance prescription is filled. *Supra*, section II.A.; *e.g.*, Tr. 228, 506, 518, 553, 556; *accord id.* at 588 (Respondent’s owner and PIC testifying about the duty to document the resolution of a red flag).

IV. DISCUSSION

A. The Controlled Substances Act

Under Section 304 of the CSA, “[a] registration . . . to . . . distribute[] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined by such section.” 21 U.S.C. 824(a)(4). In the case of a “practitioner,” which is defined in 21 U.S.C. 802(21) to include a “pharmacy,” Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(f)(1-5). The five factors are considered in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15,227, 15,230 (2003).

According to Agency decisions, the Agency “may rely on any one or a combination of factors and may give each factor the weight [it] deems appropriate in determining whether” to revoke a registration. *Id.*; *see also Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi v. Drug Enf’t Admin.*, 841 F.3d 707, 711 (6th Cir. 2016); *MacKay v. Drug Enf’t Admin.*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. U. S. Drug Enf’t Admin.*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. Drug Enf’t Admin.*, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while the Agency is required to consider each of the factors, it “need not make explicit findings as to each one.” *MacKay*, 664 F.3d at 816

(quoting *Volkman*, 567 F.3d at 222); *see also Hoxie*, 419 F.3d at 482. “In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant’s misconduct.” *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

According to DEA regulations, “[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.” 21 CFR 1301.44(e).

In this matter, while all of the 21 U.S.C. 823(f) Factors have been considered, the Government’s evidence in support of its *prima facie* case is confined to Factors Two and Four.¹² Government’s Proposed Findings of Fact and Conclusions of Law, at 18. The Government presented a *prima facie* case based on Factors Two and Four, and portions of the testimony of Respondent’s owner and PIC actually admit, even if unintentionally, to foundational violations of federal law. 21 CFR 1306.04(a), *supra*, sections II.A., II.B., and III. Accordingly, the Agency finds that Respondent’s continued registration is inconsistent with the public interest. 21 U.S.C. 824(a)(4) and 823(f)(2) and (f)(4).

B. Factors Two and/or Four – The Respondent’s Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

Allegation that Respondent’s Registration Is Inconsistent with the Public Interest

According to the CSA’s implementing regulations, a lawful prescription for controlled substances is one that is “issued for a legitimate medical purpose by an individual practitioner

¹² Neither Respondent nor the Government argues that it offered evidence relevant to Factors One, Three, or Five. Although the Agency considered Factors One, Three, and Five, it finds that none of them is relevant to this adjudication, as the RD recommends. RD, at 30, n.32.

acting in the usual course of his professional practice.” 21 CFR 1306.04(a); *see Gonzales v. Oregon*, 546 U.S. 243, 274 (2006); *see also* Tex. Health & Safety Code § 481.074.

Respondent engaged a skillful team and defended itself against the OSC’s allegations. As already noted, the record evidence, including testimony of Respondent’s owner and PIC, contains substantial evidence of violations of applicable law. Those violations go to the heart of this Agency’s law enforcement mission. *Supra*, sections II.A., II.B., and III; *infra*, sections IV.B. and V.

Having thoroughly analyzed the record and applicable law, the Agency finds substantial record evidence, including testimony and admissions of Respondent’s owner and PIC, that (1) Respondent filled controlled substance prescriptions containing red flags, including red flags explicitly listed in Texas law, such as pattern prescribing, cash payment, distance, and shared address and (2) Respondent filled these controlled substance prescriptions without resolving, and documenting the resolution of, the red flags on them.¹³ *Supra*, sections II.A., II.B., and III. Indeed, Respondent’s owner and PIC repeatedly denied that controlled substance prescriptions at issue in this proceeding even included a red flag. *Supra*, section II.B. Substantial record

¹³ *E.g.*, Government Exhibit (hereinafter, GX) 3, at 3 (customer AC, February 29, 2020, pattern prescribing); GX 3, at 6 (customer AC, October 6, 2020, pattern prescribing); GX 4, at 4 (customer AM, September 21, 2020, pattern prescribing); GX 5, at 2 (customer AR, July 8, 2020, pattern prescribing); GX 12, at 2 (customer DG, July 13, 2019, distance); GX 15, at 2 (customer FL, June 22, 2020, pattern prescribing); GX 16, at 3 (customer FA, August 3, 2020, pattern prescribing); GX 17, at 2 (customer GG, August 5, 2020, pattern prescribing); GX 18, at 2 (customer IS, March 8, 2019, pattern prescribing); GX 18, at 5 (customer IS, March 29, 2019, pattern prescribing); GX 18, at 8 (customer IS, January 6, 2020, pattern prescribing); GX 18 at 11 (customer IS, September 3, 2020, pattern prescribing); GX 19, at 2 (customer IS, October 5, 2020, pattern prescribing); GX 20, at 109 (customer IG, October 12, 2020, pattern prescribing); GX 21, at 3 (customer IG, September 22, 2020, pattern prescribing); GX 22, at 2 (customer JB, February 7, 2019, distance); GX 22, at 4 (customer JB, May 16, 2019, distance); GX 22, at 6 (customer JB, March 20, 2020, distance); GX 23, at 2 (customer JS, July 8, 2020, pattern prescribing); GX 24, at 3 (customer JR, October 8, 2020, pattern prescribing); GX 25, at 2 (customer JC, January 23, 2020, shared address and pattern prescribing with customer AL, January 23, 2020) alone and in conjunction with GX 60, at 1 (shared address); GX 26, at 3 (customer JL, July 24, 2020, pattern prescribing); GX 31, at 3 (customer LO, October 7, 2020, pattern prescribing) alone and in conjunction with GX 50, at 1 (cash); GX 35, at 3 (customer MO, July 8, 2020, pattern prescribing); GX 37, at 2 (customer MN, August 26, 2020, pattern prescribing); GX 41, at 5 (customer PG, January 4, 2020, pattern prescribing) alone and in conjunction with GX 56, at 1 (cash); GX 41, at 8 (customer PG, March 3, 2020, pattern prescribing) alone and in conjunction with GX 56, at 1 (cash); GX 42, at 5 (customer RT, February 11, 2020, pattern prescribing); GX 45, at 2 (customer TS, February 20, 2020, distance); GX 46, at 18 (customer YG, January 15, 2019, pattern prescribing) alone and in conjunction with GX 51, at 1 (cash); and GX 46, at 24 (customer YG, February 29, 2020, pattern prescribing) alone and in conjunction with GX 51, at 1 (cash).

evidence of any one of the founded controlled substance prescription violations is sufficient for the Agency to revoke Respondent's registration.

Prior Agency decisions consistently find that controlled substance prescriptions with these red flags are so suspicious as to support a finding that the pharmacists who filled them violated their corresponding responsibility due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy. 21 CFR 1306.04(a); *see also, e.g.*, Tex. Health & Safety Code §§ 481.074, 481.128; *The Pharmacy Place*, 86 FR at 21,013 (collecting Agency decisions).¹⁴ Indeed, the testimony of Respondent's owner and PIC, during which he spoke at length about why red flags, that are explicitly listed in Texas law as such, are not red flags, is record evidence that Respondent was willfully blind to red flags on the prescriptions it filled. *Supra*, section II.B. Accordingly, the Agency finds that there is substantial record evidence of violations of applicable law and, therefore, that it is appropriate to sanction Respondent for these violations. *Supra*, sections II, III, and IV.

Summary of Factors Two and Four

Respondent did not successfully rebut the Government's *prima facie* case, established by substantial record evidence, that it violated applicable law by filling controlled substance prescriptions without resolving and documenting the resolution of the red flags on them. 21 CFR 1306.04(a), 22 TAC § 291.29. Accordingly, the Agency finds that Respondent violated applicable law, supporting the revocation of its registration. 21 U.S.C. 824(a)(4).

V. SANCTION

¹⁴ Agency decisions have consistently found that prescriptions with the same red flags at issue here were so suspicious as to support a finding that the pharmacists who filled them violated the Agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy. 21 CFR 1306.04(a); *see, e.g.*, *Morning Star Pharmacy and Medical Supply I*, 85 FR 51,045, 51,061 (2020) (pattern prescribing; distance; cash payments; high doses/quantities of high-alert controlled substances); *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, 83 FR 10,876, 10,898 (2018), *pet. for rev. denied*, 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; cash payments); *Hills Pharmacy*, 81 FR 49,816, 49,836-39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances); *The Medicine Shoppe*, 79 FR 59,504, 59,507, 59,512-13 (2014) (unusually large quantity of a controlled substance; pattern prescribing).

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest due to its numerous violations pertaining to controlled substances, the burden shifts to the Respondent to show why it can be entrusted with a registration. *Garrett Howard Smith, M.D.*, 83 FR 18,882 (2018). Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *Id.* A registrant's acceptance of responsibility must be unequivocal. *Id.* In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* In addition, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* DEA Administrators have also considered the need to deter similar acts by the respondent and by the community of registrants. *Id.*

Regarding these matters, there is no record evidence that Respondent, or its owner and PIC, takes responsibility, let alone unequivocal responsibility, for the founded violations.¹⁵ Instead, the testimony of Respondent's owner and PIC is replete with unsupported and undocumented assertions about why controlled substance prescriptions evidencing what Texas law labels as "red flag factors" are not red flags at all, typically then followed by the incantation that, if there is no red flag, there is nothing to document. *Supra*, sections II.B. and IV.B; *see also* Tr. 793 (testimony of Respondent's owner and PIC regarding a prescription that, according to the customer's profile, shows "a pretty bad drug interaction," and his assertion that "you don't necessarily have to document that" while acknowledging that "I know we say document,

¹⁵ Respondent's owner and PIC "accept[ed] responsibility" for putting a customer's ID address as the main address in the patient profile instead of the customer's local, Texas, address. Tr. 763-64. While this testimony might sound like an acceptance of responsibility, it is not the requisite acceptance of responsibility required by past Agency decisions. The Agency interprets this testimony as a way for Respondent's owner and PIC to minimize the illegality of Respondent's actions by highlighting that the particular customer was in the military and, for that reason, had multiple addresses, and by stating his "understanding" that the customer was "living locally" when he presented the controlled substance prescription instead of resolving and documenting the resolution of the red flag. *Id.*

document, but a lot of things are expected as a plan of care for patients that are very important that are not documented”) in conjunction with 22 TAC § 291.33(c)(2)(A)(ii); Tr. 805 (testimony of Respondent’s owner and PIC that “there was really nothing to document because, typically, with red flags, the things we want to document is if you think the prescription is fraudulent”); *id.* at 815 (testimony of Respondent’s owner and PIC that a controlled substance prescription for codeine cough syrup is medicine for a “communicable disease, . . . I don’t think any pharmacist would really see that as a red flag”) in conjunction with 22 TAC § 291.29(f)(3) (listing prescriptions for cough syrups containing codeine, a treatment for a communicable disease, Tr. 823, as a “red flag factor”). The Agency finds that most of the testimony of Respondent’s owner and PIC evidences, at best, a deep and endemic misunderstanding of Texas and federal law.

Testimony of Respondent’s owner and PIC about what he is “doing differently regarding documentation now,” given the OSC, may sound like it describes Respondent’s proposed remedial measures, but it does not.¹⁶ Tr. 845. The testimony of Respondent’s owner and PIC in response to this question starts with his statement that he has “changed a few things” with “rules to go above and beyond what is required.” *Id.* He testified that, “in a lot of cases where patients are coming from far,” he “will document more than I like to document just so that way the situations like this is prevented,” elaborating that he told all of his employees that “what we need is the local address” noted as the “primary address.”¹⁷ Tr. 846-47. This testimony appears to be more indicative of an attempt to avoid law enforcement attention in the future rather than of an accurate understanding of Texas and federal legal requirements, to recognize, resolve, and document the resolution of red flags, and a commitment to comply with them.

¹⁶ In any event, actual remedial measures are insufficient without an unequivocal acceptance of responsibility. *Brenton D. Wynn, M.D.*, 87 FR 24,228, 24,261 (2022); *see also Michael T. Harris, M.D.*, 87 FR 30,276, 30,278 (2022) (collecting Agency decisions).

¹⁷ Respondent’s owner and PIC also testified in response to this question that he now documents the “BMIs” (body mass indexes) of customers who present phentermine prescriptions to be filled, elaborating “just so we know on our own that the doctor’s doing the right thing and also that the patients really need the medication.” Tr. 845. He testified that he now will also ask the doctor for the patient’s BMI and document it. *Id.* at 845-46. Even if this BMI-related testimony constitutes remedial measures, which it does not, remedial measures are insufficient without an unequivocal acceptance of responsibility.

In sum, the record supports the imposition of a sanction because Respondent, through its owner and PIC, did not unequivocally accept responsibility and because Respondent, through its owner and PIC, has not convinced the Agency that it can be entrusted with a registration.

The interests of specific and general deterrence weigh in favor of revocation. The testimony of Respondent's owner and PIC repeatedly denied the existence of any legal violations, let alone accepted unequivocal responsibility for them. *See, e.g., supra*, sections II.B., IV.B., and V. Respondent, through its owner and PIC, has not convinced the Agency that it understands that its controlled substance prescription filling fell short of the applicable legal standards and that this substandard controlled substance prescription filling has serious negative ramifications for the health, safety, and medical care of individuals who come to it with controlled substance prescriptions. *See, e.g., Garrett Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018) (collecting cases) ("The egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction."). As such, it is not reasonable to believe that Respondent's future controlled substance prescription filling and recordkeeping will comply with legal requirements. Further, given the foundational nature and vast number of Respondent's violations, a sanction less than revocation would send a message to the existing and prospective registrant community that compliance with the law is not a condition precedent to maintaining a registration.

Accordingly, I shall order the sanction the Government requested, as contained in the Order below.

ORDER

Pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. FL2190332 issued to Lewisville Medical Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I hereby deny any pending application of

Lewisville Medical Pharmacy to renew or modify this registration, as well as any other pending application of Lewisville Medical Pharmacy for registration in Texas. This Order is effective **[insert Date Thirty Days From the Date of Publication in the Federal Register]**.

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on September 26, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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